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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,606	10/16/2001	Barry E. Rothenberg	24065-004CON	6347

7590 08/28/2002  
MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.  
One Financial Center  
Boston, MA 02111

EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/981,606

Applicant(s)

ROTHENBERG ET AL.

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to a method of determining a mutation in exon 2 of an HFE nucleic acid, classified in class 435, subclass 6.
  - II. Claims 25-33, drawn to a method of determining a mutation in an intron of an HFE genomic DNA, classified in class 435, subclass 6.
  - III. Claims 34-48, drawn to a method of determining a mutation in an HFE polypeptide, classified in class 435, subclass 7.1.
  - IV. Claims 49-52, drawn to a nucleic acid molecule that encodes an HFE polypeptide, kit, classified in class 536, subclass 23.1.
  - V. Claim 53, drawn to a kit for detecting a mutation in exon 2 of an HFE nucleic acid comprising oligonucleotide primers, classified in class 435, subclass 287.2.
  - VI. Claims 54-56, drawn to a purified HFE polypeptide, classified in class 530, subclass 369.
  - VII. Claim 57, drawn to a kit for detecting a mutation utilizing antibodies that bind to an epitope of a mutant HFE polypeptide, classified in class 435, subclass 287.2.
  - VIII. Claim 58, drawn to a kit for detecting a mutation utilizing antibodies that bind to an epitope of a wild type HFE polypeptide, classified in class 435, subclass 287.2.

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2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are drawn to a method of determining a mutation. Invention I is unrelated from Inventions II and III because it is drawn to a method of determining a mutation in exon 2 of an HFE nucleic acid. Invention II is unrelated from Inventions I and III because it is drawn to determining a mutation in an intron of an HFE genomic DNA. Invention III is unrelated from Inventions I and II because it is drawn to determining a mutation in an HFE polypeptide.

Inventions IV, V, VII, and VIII are drawn to a kit for detecting a mutation. Invention IV is unrelated from Inventions V, VII, and VIII because it is drawn to a nucleic acid encoding an HFE polypeptide and kit thereof. Invention V is unrelated from Inventions IV, VII, and VIII because it is drawn to a kit for detecting a mutation comprising oligonucleotide primers where the first primer is 5' to exon 2 and the second primer is 3' to exon 2 of an HFE nucleic acid. Invention VII is unrelated from Inventions IV, V, and VIII because it is drawn to a kit for detecting a mutation utilizing an antibody that binds to an epitope of a mutant HFE polypeptide. Invention VIII is unrelated from Inventions IV, V, and VII because it is drawn to a kit for detecting a mutation utilizing an antibody that binds to an epitope of a wild type polypeptide.

Invention VI and Inventions I, II, III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group VI is drawn to a purified HFE polypeptide which may

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be used in assay technology, may serve as an HFE agonist or may function as a transferrin receptor antagonist whereas Groups I, II, and III are drawn to a method of identifying a mutation.

Invention VI and Inventions IV, V, VII, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group VI is drawn to a purified HFE polypeptide which may be used in assay technology, may serve as an HFE agonist or may function as a transferrin receptor antagonist whereas Groups IV, V, VII, and VIII are drawn to a kit for detecting a mutation.

Invention I and Inventions IV, V, VII, VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process (MPEP § 806.05). In this case, the method of determining a mutation in exon 2 of an HFE nucleic acid as claimed in Invention I can be practiced by another materially different apparatus such as a kit containing restriction enzyme Bst4C I.

Invention II and Inventions IV, V, VII, VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed

can be used to practice another and materially different process (MPEP § 806.05). In this case, the method of determining a mutation in an intron of an HFE genomic DNA as claimed in Invention I can be practiced by another materially different apparatus such as a kit containing restriction enzyme Bst4C I.

Invention III and Inventions IV, V, VII, VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process (MPEP § 806.05). In this case, the method of determining a mutation in an HFE polypeptide as claimed in Invention I can be practiced by another materially different apparatus such as a kit containing restriction enzyme Bst4C I.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

### CONCLUSION

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is [shar.hashemi@uspto.gov](mailto:shar.hashemi@uspto.gov). However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

July 31, 2002

*Jeffrey Siew*  
JEFFREY SIEW  
PRIMARY EXAMINER  
*8/26/02*